

### **REMARKS**

Applicants respectfully request reconsideration and allowance of claims 1-20 that are pending in the above-identified patent application. Applicants have amended claims 1, 7-10, and 16-18 to place them in better form. No new matter is added by way of these claim amendments.

#### **Allowable Subject matter**

Applicants acknowledge with appreciation that at page 20 of the Office Action, the Examiner deemed claim 9 as containing patentable subject matter.

#### **Objection to the Drawing**

At pages 2-3 of the Office Action, the Examiner objected to the drawing alleging that they do not show the "bore (25)" as referenced in the specification. Applicants submit, however, that the specification as filed does not refer to a bore (25), and thus request that the objection be withdrawn. The Examiner has also objected to the drawings alleging that FIGS. 5-9 are unclear. In response, Applicants have requested that the Examiner accept the proposed new drawings, which include FIGS. 5-9, attached hereto and labeled REPLACEMENT SHEET(S). These new drawings are believed to meet the clarity requirements. In view of the above, Applicants respectfully request withdrawal of the drawing objections.

#### **Objection to the Specification**

At pages 3-6 of the Office Action, the Examiner objected to the specification alleging that claims 8-10 and 18 lack antecedent basis. Applicants submit that the claim amendments herein render the Examiner's objection moot, as the claim language that the Examiner alleges is not supported has been amended. The Examiner has also objected to the specification on formal grounds. In response, Applicants have requested that the Examiner accept the attached substitute specification under 37 C.F.R. § 1.125(b) and M.P.E.P. § 608.01(q) in lieu of a listing of changes to be made to the original literal translation of the priority application. No new matter has been added by way of the specification amendments. In view of the above, Applicants respectfully request

withdrawal of the objections to the specification.

### **Double Patenting**

At pages 6-9 of the Office Action, the Examiner rejected claims 1, 4, 5, 7, 12, 14, and 15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over certain claims of U.S. Patent Application No. 10/982,991. In response, Applicants have filed herewith a terminal disclaimer pursuant to 37 C.F.R. § 1.321(c), which may be used to overcome the obviousness-type double patenting rejection.

### **Rejection Under 35 U.S.C. § 112**

At page 9 of the Office Action, the Examiner rejected claims 8-10 and 18 under 35 U.S.C. § 112 as being unclear or not supported by the specification. Applicants submit that the claim amendments herein render the Examiner's rejection moot, as the claim language that the Examiner alleges is not supported has been amended and is believed clear and supported by the specification as filed. In view of the above, Applicants respectfully request withdrawal of the rejections under § 112.

### **Rejections Under 35 U.S.C. § 102(b)**

At pages 9-16 of the Office Action, the Examiner rejected claims 1-8 and 10-15 under 35 U.S.C. § 102(b) as being anticipated by WO 97/12687. Applicants respectfully traverse the Examiner's rejection.

Each of independent claims 1 and 7 of the instant application require one or more surfaces of the output side of the nozzle to include at least one of microstructures and nanostructures.

By way of example, such microstructures and nanostructures are described at pages 5-8 of the patent specification as filed and are shown in FIGS. 5-9. Again, by way of example, claims 1 and 7 cover structures in which the microstructures and/or nanostructures are disposed on at least a portion of the surface of the conical recess 81, the end face the nozzle holder 78, etc. The reason for the microstructures and/or nanostructures is to reduce the amount of fluid that would otherwise build

up on a smooth surface. Indeed, without the microstructures and/or nanostructures, small amounts of liquid may accumulate on such surfaces, which is called the "mouthpiece fraction". Such accumulation leads to a certain variability in the amount of liquid dispensed through the nozzle, and may also cause contamination of the outer surface of the nozzle system or of the mouthpiece, which may in turn affect the pharmaceutical quality of the next application of mist through the nozzle.

The WO 97/12687 reference does not disclose microstructures and nanostructures located on the surface(s) as claimed, which is not surprising because that reference discloses the formation of channels, inlet ports and outlet ports using microtechnology. Applicants submit, and establish below, that the structure and application of the channels, inlet ports and outlet ports of the WO 97/12687 reference are not the same as the microstructures and nanostructures on the particular surfaces of the nozzle as claimed. At page 9 of the WO 97/12687 reference, U.S. Patent No. 5,472,143 ("the '143 patent") is cited as disclosing the "microstructured nozzle members". A review of the '143 patent, however, reveals that the structure and purpose of the disclosed "microstructures" is to form small cross-sectional channels 15, filters 13, outlet ports 14, etc. In other words, the "microforming art" employed by the '143 patent (and thus the WO 97/12687 reference) is disclosed to produce the actual apertures and orifices that make the channels 15, filters 13, outlet ports 14:

A nozzle assembly in accordance with the invention can readily be formed as a laminated unitary construction from components which have had the appropriate channels, inlets and outlets pre-formed therein by laser, chemical etching, photo-resist or other surface engraving techniques well known in the microforming art to achieve simple but accurately reproducible components having substantially flat opposing faces. These components can be secured together by diffusion bonding, adhesion, welding, clamping or other suitable techniques for securing them together in sealing engagement, optionally with sealing rings or other sealing interfaces between the members by simple assembly techniques.

(The '143 patent at col. 4, lines 12-24.)

In contrast, the microstructures and nanostructures as claimed refer to the characteristics of a particular surface, such as the surface of the conical recess 81. In other words, the surface itself has microstructures and nanostructures thereon – as opposed to a structure having a hole therethrough that is of a micro-size as disclosed in the WO 97/12687 reference (and by extension the '143 patent).

Accordingly, Applicants submit that the WO 97/12687 reference fails to disclose all of the features of the inventions as claimed in independent claims 1 and 7 (and their dependent claims) of

the instant application. Withdrawal of the 35 U.S.C. § 102(b) rejection is therefore requested.

### **Rejections Under 35 U.S.C. § 103(a)**

At pages 16-20 of the Office Action, the Examiner rejected claims 16-20 under 35 U.S.C. § 103(a) as being unpatentable over WO 97/12687 in view of U.S. Patent No. 5,823,436 ("the '436 reference"). Applicants respectfully traverse the Examiner's rejection. As discussed above, the WO 97/12687 reference fails to disclose the type of microstructures and nanostructures recited in base claims 1 and 7. The '436 reference merely discloses the same types of small orifices as in the WO 97/12687 reference and the '143 patent discussed above. Thus, the '436 reference fails to remedy the deficiencies of the WO 97/12687 reference.

Accordingly, Applicants submit that the combined teachings of the WO 97/12687 reference and the '436 reference fail to disclose all of the features of the inventions as claimed in independent claims 1 and 7, or dependent claims 16-20 of the instant application. Withdrawal of the 35 U.S.C. § 103(a) rejection is therefore requested.

### **Conclusion**

In view of the foregoing, Applicant submits that the instant claims are in condition for allowance. Early and favorable action is earnestly solicited. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

Dated: April 27, 2007

Respectfully submitted,

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